APR 1 6 2002

Premarket Notification (510(k)) Summary

K020528

510(k) Number: _____

Product Name: IntraStent® Mega™ LD (Large Diameter) Stent (Biliary Indication)
IntraStent® Max™ LD (Large Diameter) Stent (Biliary Indication)

Common Name: biliary stent

Class: Class II, 21 CFR 876.5010

Submitter's Name:
Sulzer IntraTherapeutics Inc.
651 Campus Drive
St. Paul, MN 55112

Official Contact:
Glen D. Smythe
Sterilization/Regulatory Affairs Associate
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Summary Preparation Date: 15 February 2002

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission for a modification to the IntraStent® Stent.

The IntraStent Mega and Max LD stent are intended as a palliative treatment of malignant neoplasms in the biliary tree.

The IntraStent Mega and Max LD Stents are balloon expandable stainless steel stents with an open lattice design. The device is provided unmounted, to be manually crimped onto a noncompliant PTA balloon catheter for biliary stent expansion of choice by the physician. Upon balloon inflation the crimped stent expands to conform to the duct inner luminal surface and retains the expanded state upon balloon deflation.

Summary of technological characteristics: The IntraStent Mega and Max LD stents provide a larger version the IntraStent™ Stent (K991929), allowing expanded diameters of 9-12mm and 12mm. The IntraStent devices are balloon expandable stents fabricated by cutting an engineered series of slots/apertures into a 316L stainless steel hypotube. The cuts are made with a laser. The IntraStent devices are cleaned, electro-polished, packaged in a double sterile barrier and sterilized. The IntraStent devices are ethylene oxide sterilized and are provided unmounted.

K020528

510K Summary (continued)

The IntraStent devices incorporate the use of manual compression using one's thumbs and forefingers to compress the stent onto the delivery balloon catheter.

Bench tests were performed to verify that the IntraStent Mega and Max LD stents met the same performance characteristics as the predicate IntraStent™ Stent (K991929).

The IntraStent is substantially equivalent* to the currently marketed IntraStent stent (K991929) and the IntraStent DoubleStrut LD (K993904) as a palliative treatment for malignant strictures of the biliary tree. As demonstrated, the modified IntraStent stent is identical in materials, indication for use, and technological characteristics. Performance testing (bench) further supports a substantial equivalence claim. The collective evidence therefore provides assurance that the IntraStent® Mega™ LD and IntraStent® Max™ LD meet the requirements that are considered acceptable for the intended use.

*This document uses the term "substantial equivalence" as intended in 21 CFR 807.87, and not as defined in Title 36 of the US Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2002

Mr. Glen D. Smythe
Sterilization/Regulatory Affairs Associate
Sulzer IntraTherapeutics
651 Campus Drive
ST. PAUL MN 55112

Re: K020528
Trade/Device Name: IntraStent® Mega™ LD (Large Diameter) Stent – Biliary Indication
IntraStent® Max™ LD (Large Diameter) Stent – Biliary Indication
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: March 21, 2002
Received: March 22, 2002

Dear Mr. Smythe:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that these devices will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the devices' labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

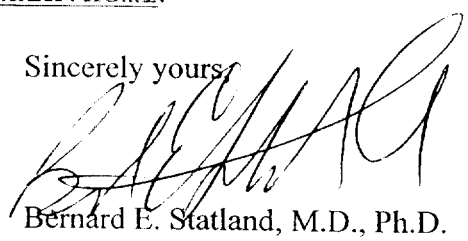
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and permits your devices to proceed to the market. This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the devices' labeling.

If you desire specific information about the application of other labeling requirements to your devices (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020528

Device Name: IntraStent® Mega™ LD (Large Diameter) Stent – Biliary Indication, and IntraStent® Max™ LD (Large Diameter) Stent – Biliary Indication

FDA's Statement of the Indications For Use for devices:

The IntraStent® Mega™ LD (Large Diameter) Stent – Biliary Indication and the IntraStent® Max™ LD (Large Diameter) Stent – Biliary Indication are intended as a palliative treatment of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

David G. Jayne

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020528